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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,431	06/22/2005	Mari Ann Kulseth	PN0273	4644

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EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,431	KULSETH, MARI ANN	
	Examiner	Art Unit	
	THOMAS S. HEARD	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *22 July 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-9, in the reply filed on 10/29/2007 is acknowledged. The traversal is on the ground(s) that *"claims to different categories will be considered to have unity of invention if the claims are drawn to the following combination of categories: ... (2) product and a process of use of said product." Applicants submit that in the instant application, Group I and Group II of the claims are directed to such combination of product and method of use. Thus, the claims of the instant application have the unity of invention.*' This is not found persuasive because the expression "special technical feature" refers to those features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Thus, a feature found in the prior art cannot be considered to be a special technical feature. Because the peptides of Claim 1 are known in the art by reference US Patent 6,255,458, it cannot be considered a special technical feature.

Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are pending, Claims 1-9 are examined on the merits. Claim 10 is withdrawn for reason stated supra.

Applicants have elected the species according to claim 1, formula (I) and (II), the peptide SEQ ID No. 1: Cys-Ser-Tyr-Tyr-Ser-Asp-Gly-Val-Tyr-Asp-Cys. According to

claim 3 and Formula (III), the Applicants have elect: V is peptide SEQ ID No. 1, as elected above, L is an amide bond, Z is a chelating agent of formula e, M is ^{99m}TC.

Applicants elected species appears free of the prior art. The Examiner has moved on to the remaining species in Claim 2 and has found SEQ ID NOs: 1-14 free of the prior art. The Examiner has moved on to the generic of Formula (I) and (II) of Claim 1 and art has been applied to a species of the genus claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, Z^1-X^1-Tyr-X^3(Ala or Ser)-Asp-Gly-X^7-(Tyr or Phe)-Asp-Y^1 is not understood because there is not dash indicating whether a bond is present between X3 and Ala or if X3 can include Ala or Ser.

In Claim 1, residue is vague and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:
"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

materials." Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In Gostelli, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to compounds of Formula (I) or (II), whereby the Markush of (I) is Z^1-X^1-X^2-X^3-X^4-X^5-Gly-X^7-X^8-X^9-Z^2-Y^1 and (II) is Z^1-X^1-Tyr-X^3-(Ala or Ser)-Asp-Gly-X^7- (Tyr or Phe)-Asp-Y^1. Z^1 represent an amino acid residue capable of forming a disulphide bond, preferably a cysteine or a homocysteine residue, or a residue capable of forming a thioether preferably the residue is Q-C(=O) wherein Q represents $(CH_2)n$ or $(CH_2)n$-C_6H_4 where n represents a positive integer 1 to 10 or is

absent and Z.sup.2 represent an amino acid residue capable of forming a disulphide bond, preferably a cysteine or a homocysteine residue or is absent Y_1 represents 1-10 amino acids or is absent. The claims are further drawn to a targetable diagnostic and/or therapeutically active agent of formula (III) V-L-Z Formula (III) wherein the vector V is a peptide according to claim 1, L represents a bond, a spacer or a linker and Z represents an antineoplastic agent, a reporter moiety or a group that optionally can carry an imaging moiety M. An agent as claimed in claim 3 where each reporter (Z) can carry a multiplicity of vectors V. A pharmaceutical composition comprising an effective amount of a compound of general Formula (III) or a salt thereof, together with one or more pharmaceutically acceptable adjuvants, excipients or diluents for use in enhancing image contrast in in vivo imaging or for treatment of a disease.

(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to conception, experimental design and data interpretation, and chemical synthesis.

(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:

Linear and cyclic peptide that bind to the heparin binding domain of vegf and vegfr-2.

(5) Method of making the claimed invention:

Chemical synthesis.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is

unquestionable that claim 1, 3, 7, 8, and 9 are a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of Markush group or formula that is described in functional language.. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. "MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. There are fourteen examples found in the specification and in Claim 3 for example but there is insufficient description of a common core structure for V-L-Z of Claim 3, a multiplicity of vector for Claim 7, and that would allow one of skill in the art to practice the invention as claimed. Applicants have described the peptides in both linear and cyclic manner, but have not described the chelating agents, reporter moieties, or antineoplastic agents that could be made with a multiplicity of vectors, or with Formula (IV). A group that can optionally carry a imaging moiety lacks written description because if it does not carry an imaging moiety, it is just a group and lacks written description. The term residue coupled with amino acid also lacks written description as amino acid would be understood on it own. Chelating groups' a-e have written description, but that of Formula (IV) lacks written description on how to attach it to the linear or cyclic peptides. Further, the intended use of treatment of

a disease is an extremely broad genus that could encompass nearly any malady known to man. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lonberg et al, US Patent 6,255,458. In instant invention is drawn to compounds of Formula (I), that of Z^1-X^1-X^2-X^3-X^4-X^5-Gly-X^7-X^8-X^9-Z^2-Y^1.

Lonberg discloses the peptide:

YCARHYYGSG SYDYYYYGMD VWGQGTTVTV SSGSAS as SEQ ID NO 281.

For this peptide, Z^1, Z^2, and Y^1 are absent. X^1 is H, X^2 Y, X^3 is Y, X^4 G, X^5 is G, X^7 is S, X^8 is Y, and X^9 is D. The language of Claims 1 is considered open and thus can contain other amino acids beyond those indicated by Formula (I) or (II). Consisting is the only recognized "closed" language found in the MPEP, and unless amended to consisting, Claims 1 will be interpreted as open, see 2111.03 [R-3], Transitional Phrases.

Therefore, the invention as claimed is anticipated by the prior art.

Conclusion

Claim 2 is objected to as being dependent on a rejected claim. No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas S. Heard** whose telephone number is **(571) 272-2064**. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

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